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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/558,038	04/26/2000	Gerhard Bienhaus	P101614-00001	9496

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	5

DATE MAILED: 05/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/558,038	BIENHAUS ET AL.	
	Examiner	Art Unit	
	Frank Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 13-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 13-35 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, and 34 are rejected over the recitation of the phrase, "near". The term "near" in claims 13 and 34 is a relative term which renders the claims indefinite. The term "near" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the claim is vague and indefinite.

Regarding claim 17, the phrase "may be" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Regarding claim 19, the phrase "micrometal" renders the claim vague and indefinite. It is not clear whether the metal is micro in shape or size or is micro in weight or micro according to atomic number or molecular mass. The metes and bounds of the claim is vague and indefinite.

Claims 20-21 are rejected over the recitation of the phrase "about 0.5 to 5 g" and "about 1g to 4 g". Regarding claim 20, it is not clear if 0.45- 0.55 g to 5 g is claimed or 0.45 -0.55 g to 4.5 g is claimed or 0.45 -0.55 g to 5.5 g is claimed or all of them are claimed. Regarding claim

21, it is not clear if 0.09- 1.1 g to 4 g is claimed or 0.09- 1.1 g to 3.6 g is claimed or 0.09- 1.1 g to 4.4 g is claimed or all of them are claimed. The metes and bounds of the claims are vague and indefinite.

Claim 28 is rejected over the recitation of the phrase, "higher". The term "higher" in claim 28 is a relative term which renders the claim indefinite. The term "higher" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the claim is vague and indefinite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 13-18, 22-28, and 30-35 are rejected under 35 U.S.C. 102 (e) as being anticipated by Reeve (U.S. Patent 5,523,231) (June 4, 1996).

Reeve teaches a method of isolating nucleic acid from biological compartments of a fluid sample (Abstract) comprising the steps of:

a) incubating the sample in a sample processing vessel with magnetic particles which magnetic particles are capable of binding with the biological compartments (Abstract and Figures 1-2, especially step 1, and Examples 1-8);

b) positioning at least one magnet near an outside wall of the sample processing vessel such that the magnet holds the magnetic particles against an inside wall of the sample processing vessel (Figures 1-2, especially step 4);

c) removing the remaining fluid, from which the biological compartments have been separated, from the sample processing vessel (Figures 1-2, especially step 5);

d) introducing a second fluid into the sample processing vessel (Figures 1-2, especially step 6);

e) resuspending the magnetic particles in the second fluid by eliminating the magnetic force which held the magnetic particles against the inside wall of the sample processing vessel, and shaking the sample processing vessel (Column 4, lines 31-36);

f) lysing the biological compartments to form a lysis mixture (Claims 4-5); and

g) isolating the nucleic acids from the lysis mixture (Column 4, lines 36-44 and Claims 4-5).

Reeve teaches a method, wherein essentially all of the magnetic particles have a diameter of 2.8 micrometer to 200 micrometer (Column 2, lines 59-61 and Column 8, lines 52-53).

Reeve teaches a method, wherein the isolation step comprises immobilizing the nucleic acids on the magnetic particles (Figures 1-2).

Reeve teaches a method, wherein the nucleic acids to be isolated are transferred to a vessel from which they may be pipetted (Column 4, lines 39-44).

Reeve teaches a method, wherein the magnetic force is eliminated by separating by a sufficient distance the at least one magnet from the outside wall of the sample processing vessel (Column 4, lines 33-36).

Reeve teaches a method, wherein the processing vessel containing the sample is shaken during at least a portion of the incubation step to facilitate binding (Column 4, lines 31-36).

Reeve teaches a method, wherein the magnetic force is eliminated and the sample processing vessel is shaken simultaneously (Column 4, lines 31-36 and Example 6 and Column 5, lines 36-38).

Reeve teaches a method, wherein the steps a) to g) are repeated until the biological compartments have reached a desired level of purity (Claims 4-5).

Reeve teaches a method, wherein the fluid sample is a body fluid which is blood (Example 8, especially column 11, lines 45-50).

Reeve teaches a method, wherein the nucleic acids are present and detected in the sample reaction vessel in a block throughout the removing, resuspending and lysing steps (Examples 6-8 and Claims 4-5).

Reeve teaches a method, wherein the lysis mixture is warmed to a temperature around room temperature or higher (Example 7, column 10, lines 65-67).

Reeve teaches a method, wherein the lysis mixture is cooled under conditions that make it possible to isolate or hybridize the nucleic acids to be isolated or detected (Example 5).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 20, 21, and 29 are rejected under 35 U.S.C. 103 (a)) as being obvious over Reeve (U.S. Patent 5,523,231) (June 4, 1996).

Reeve teaches all limitations of claims 13 and 27.

Reeve does not teach the specific weight of the magnets which is in the range of 0.5 g to 5 g and warming of the lysis mixture to a temperature of about 70 degree to 95 degree centigrade.

However, it is *prima facie* obvious that the selection of the specific weight of the magnet and warming of the lysis mixture to a particular temperature represent routine optimization with regard to the sizes of the biological compartments and nucleic acid molecules to be isolated and the requirement of isolation speed which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of the specific weight of the magnet and warming of the lysis mixture to a particular temperature performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

May 20, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600